



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,659	01/08/2002	L. David Waterbury	005699-512	5999

7590 03/10/2003

William H. Benz
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/043,659

Applicant(s)

WATERBURY ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 28-32, insofar as they read on the alcohol compounds of formula I, drawn to a method of treating neuropathic pain by employing the alcohol compounds of formula I or IA (i.e., R¹ is hydrogen), classified in class 576; also class 564, subclass 443+, and 280.
- II. Claims 1-14, 19, 20, and 28-32, insofar as they read on ester or thioester compounds of formula I, drawn to a method of treating neuropathic pain by employing the ester compounds of formula I or II (i.e., R¹ is an ester), classified in class 514, subclass 529, 532, 534-542; also class 585, subclass 1+.
- III. Claims 1-14, 21-22, and 28-32, insofar as they read on amide or thioamide compounds of Formula I, drawn to a method of treating neuropathic pain by employing the amide or thioamide compounds of Formula I or III (i.e., R¹ is an amide and thioamide), classified in class 514, subclass 599, 613, 617, 619, and 621; also class 562, subclass 621-625 and 800-805.
- IV. Claims 1-14, and 23-32, insofar as they read on thioether or ether compounds of Formula I, drawn to a method of treating neuropathic pain by employing the thioether or ether compounds of Formula I or IV (i.e., X

Art Unit: 1617

is O or S), classified in class 514, subclass 579, 642, 643, 715, 717, and 720; also class 569, subclass 50.

- V. Claims 33-35, insofar as they read on the alcohol compounds of formula I, (i.e., R¹ is hydrogen), drawn to a composition, classified in class 424, subclass 400-502; also class 564, subclass 443+, and 280.
- VI. Claims 33-35, insofar as they read on ester or thioester compounds of formula I (i.e., R¹ is an ester), drawn to a composition, classified in class 424, subclass 400-502; also class 585, subclass 1+.
- VII. Claims 33-35, insofar as they read on amide or thioamide compounds of Formula I (i.e., R¹ is an amide and thioamide), drawn to a composition, classified in class 424, subclass 400-502; also class 562, subclass 621-625 and 800-805.
- VIII. Claims 33-35, insofar as they read on thioether or ether compounds of Formula I (i.e., X is O or S), drawn to a composition, classified in class 424, subclass 400-502; also class 569, subclass 50.

The inventions are distinct, each from the other because of the following reasons:

Inventions V-VIII and I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of

Art Unit: 1617

treating neuropathic pain can be practiced with a materially different product such as gabapentin.

Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The invention of Groups of I, II, III, and IV are having different modes of operation since they are employing different classes of compounds which is recognized by the skilled artisan as a separate and distinct fields of arts.

Inventions V, VI, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The invention of Groups of V, VI, VII, and VIII are having different modes of operation since they are containing different classes of compounds which is recognized by the skilled artisan as a separate and distinct fields of arts.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Art Unit: 1617

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

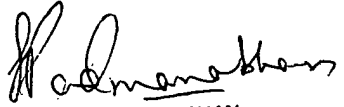
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Application/Control Number: 10/043,659

Page 6

Art Unit: 1617

San-ming Hui
March 1, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER 3/6/03